

## **REMARKS/ARGUMENTS**

Applicant has filed this response to the Office Action dated November 9, 2010. Claim 3 is pending for prosecution. Claim 3 is independent and has been amended. Support for the amendment in step (b) is found at paragraph [0046]. Applicant respectfully requests the withdrawal of all outstanding rejections and objections and the allowance of all pending claims.

### **I. Claim Rejections - 35 U.S.C. § 103**

#### **A. Obviousness**

When determining the question of obviousness, underlying factual questions are presented which include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time of the invention; (3) objective evidence of nonobviousness; and (4) the differences between the prior art and the claimed subject matter. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Moreover, with regard to the last prong of the *Graham* inquiry, “[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit.” KSR International v. Teleflex Inc., 127 U.S. 1727 (2007).

The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). The level of ordinary skill in the art in this area may be determined by looking to the references of record. In re GPAC, Inc., 57 F.3d 1573, 35 USPQ2d 1116 (Fed. Cir. 1995). The references of record in this case reveal that a moderately high level

of sophistication is present in the subject area of the instant application. Thus, Applicant submits that, as substantiated by the cited references, those with a bachelor's degree in food technology or the like would most likely be a person with ordinary skill in this field of endeavor.

With respect to objective evidence of non-obviousness, the Applicant submits that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. For at least this reason the Applicant respectfully submits that the claimed invention is not obvious in view of the cited references.

Finally, *prima facie* obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. This motivation-suggestion-teaching test informs the *Graham* analysis. "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references," there must be "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." In re Kahn, (Fed. Cir. 2006). The *KSR International* decision by the Supreme Court has not eliminated the motivation-suggestion-teaching test to determine whether prior art references have been properly combined. Rather, in addition to the motivation-suggestion-teaching test, the Court discussed that combinations of known technology that are "expected" may not be patentable. Stated in the affirmative, therefore, combinations are non-obvious and patentable if unexpected. In the present application, no single prior art reference nor any combination thereof (legitimate or otherwise) meets the claimed limitations of Applicant's invention.

## II. Rejection of Claim 3

Claim 3 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Domazakis (U.S. Pub. No. 2003/0049364) in view of Hendricks et al. (U.S. Pat. No. 5,053,237) and Brandt (Marinades "Meat" Challenges publication). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection.

The Examiner asserts that Domazakis teaches most steps of the method as claimed in claim 3 of the present invention. The Examiner admits that Domazakis does not teach the "entire muscular tissue" in relation to the meat product of the present invention. The Examiner asserts that Hendricks teaches this aspect of the present invention. The Applicant will first show how Domazakis deals with different types of meat products and therefore is inapplicable and then will discuss how Hendricks combined with Domazakis does not disclose each and every limitation of the present application.

First, Domazakis discloses a process for the preparation of emulsion-type meat-based products made of thin-chopped meat that includes the step of adding olive oil after the thin-chopped meat has been mixed with water, salt, polyphosphoric salts, preservatives, vegetable proteins, milk proteins and starch using a machine of mixture (e.g. a meat grinder or cutter) (see paragraphs [0001]-[0007], [0011]-[0012], [0031], [0038] and claim 1). However, Domazakis fails to disclose at least the following features of claim 3 of the present application:

1. *producing meat products from entire muscular tissue,*
2. *injecting entire muscular tissue with brine,*
3. *tumbling of the brine-injected entire muscular tissue,*
4. *adding olive oil to the tumbled and brine-injected entire muscular tissue, and*
5. *tumbling after the addition of olive oil (a second independent step).*

In particular, according to claim 3 of the present application, the olive oil is added to brine-injected entire muscular tissue that has been subjected to a first tumbling step, followed by a second tumbling step until complete incorporation of the olive oil is achieved. Domazakis alone or in combination with Hendricks and Brandt provides no teachings regarding these steps.

Brandt teaches the use of low temperatures for aiding tenderization (through disintegration of the muscle fiber sheath and stretching of the myofibrils), rather than the use of low temperatures for optimal incorporation of olive oil as claimed in claim 3 of the present application.

The practice of brine injection in the manufacturing of cured meat products based on whole muscular tissue is a fundamental step in the technology of cured whole muscle-based products and constitutes a well established practice in the art. The Applicant is not claiming that “brine injection” is a novel aspect of the present application, rather it is the successful incorporation of olive oil into this type of meat product that is new and novel.

The Examiner further asserts that “since Brandt discloses that tumbling or injecting are alternative methods of addition of various ingredients to the meat, one of ordinary skill in the art would have been motivated to modify Domazakis in view of Brandt and to employ tumbling or injecting instead of mixing as an alternative technique for addition of various components to the meat, as disclosed by Brandt.” The term “marinade” is not the same as an oil substance as claimed in claim 3 of the present application, while an oil substance, let alone in the herein suggested addition amounts (e.g. 5%) is by no means a typical constituent of a brine/marinade, to be used in the making of processed entire muscular tissue-based products. Brandt states that “[a] marinade generally refers to a seasoned liquid in which meat, fish and poultry are soaked to become tenderized and/or absorb flavor. A marinating solution can be as simple as salt,

phosphates and water, or more complex with flavors, seasonings, starches, vegetable or dairy proteins, acids, antimicrobials and antioxidants.” See page 1, second paragraph of Brandt. Brandt further teaches that “[...] a functional marination system includes ingredients that promote the capability of a muscle to bind water such as salt and phosphates, and those that actually bind water themselves such as soluble proteins and starches.” See page 2, third paragraph of Brandt. This teaching is far from the disclosure of adding an oil, i.e. a hydrophobic substance.

As previously stated, Domazakis discloses a process for emulsion-type meat products. The making of entire muscle tissue-based products, has nothing to do with the making of products that are chopped and minced, as they constitute a different product category governed by different technology. Meats in these two forms do not have the same properties and are therefore not comparable. A skilled person in the art would not have been tempted or able to consider Domazakis alone or in combination with other references to achieve the results of the present application. The Applicant asserts that even if the skilled person would have ignored the fact that Domazakis refers to emulsion-type sausages (e.g. frankfurter sausages, Bologna) and would be tempted to combine the teachings of Brandt with those of Domazakis, they would still not arrive at the subject matter of the present application. This is supported by the fact that there is no disclosure in either reference regarding the appropriate stage for “adding” an oil substance, to achieve a stable oil incorporation in whole muscle-based products. In particular, there is absolutely no indication in Brandt and/or Domazakis that oil is added to a tumbled and brine-injected piece of meat, using the method of this patent application and that a second independent tumbling step follows.

With regards to incorporation of unsaturated fats, Hendricks discloses the use of an “injection” mechanism that uses pressurized stream of liquid to penetrate the meat muscle. To the contrary, the method herein disclosed does not relate to such an intervention, whereby the meat pieces are penetrated and/or injected with unsaturated fats. According to the method of the present application, the meat pieces are only brine-injected, as foreseen by well established practices.

The Applicant respectfully disagrees with the Examiner’s assertion that one of ordinary skill would have been motivated to modify Domazakis and to employ the process of incorporation of olive oil in the “entire muscular tissue,” as disclosed by Hendricks. The process of oil incorporation in the meat products, as claimed in claim 3 of the present application, has nothing to do with the process disclosed in Hendricks. In particular, the process described in Hendricks is based on the use of a type of an “injection” mechanism that uses pressurized stream of liquid to penetrate the meat muscle which is a substantially different approach to that of present application, while no reference is made regarding the stability of oil incorporation in Hendricks. On the other hand, certain critical technical features underlining the method of present application are neither disclosed, nor suggested in Domazakis and/or Hendricks, namely: *i) adding olive oil to the tumbled and brine-injected entire muscular tissue, and ii) tumbling after the addition of olive oil (a second independent step).*

Even if a skilled person would have attempted to combine the teachings of Hendricks and Domazakis, they would still not have arrived at the product produced by the method of the present application. In particular, a skilled person would have rather considered to use an injectate, the way disclosed in Hendricks and having as a “binder” (see Hendricks, e.g. column 6, lines 23-25) a composition comprising a combination of ingredients as disclosed in Domazakis

(i.e. preservatives, polyphosphates, vegetable proteins, milk proteins and starch). There is no such a disclosure in the present application. This possible combination of Domazakis and Hendricks does not produce the product disclosed in the method of the present application.

In sum, it can therefore be stated that there is no teaching in the prior art as a whole, regarding the particular stage of oil addition, as disclosed in present application, as well as the second independent tumbling step. In particular, the average skilled person is neither taught to add the olive oil to the pieces of entire meat after being injected with brine and being fully tumbled, nor to conduct a second independent tumbling step. In addition, there is not a first tumbling step that continues until extraction of meat proteins has been achieved as claimed in amended claim 3 of the present invention.

Additional technical information, if considered necessary.

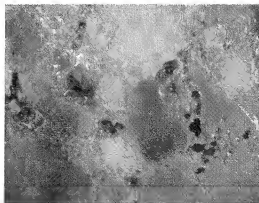
In the case of whole muscle-based products, the addition of fat (animal fat or vegetable oil) is by no means a common practice. Injection of brine is an established technique in the making of cured products based on whole muscle tissue. Brine essentially contains the curing agent and salt, the latter being of primary importance for the solubilisation of fibrillar muscle proteins (a fraction of meat proteins is salt-soluble). On the other hand, mechanical working loosens the structure of the musculature, breaks up cells, makes the absorption of the injected brine easier and increases the mobilization of the solubilized fibrillar muscle proteins. The solubilised meat proteins form a sticky exudates on the surface of the meat pieces, a thin adhesive transparent film sticking together individual pieces of muscle items, in order for the resulting product to attain its desirable morphology (ham is composed of individual items of entire muscle).

In the present application, the function of solubilized meat proteins to create the sticky exudate is again of primary importance, but in this instance the thin film sticking the muscle pieces together, has a creamy-yellowish color, due to the oil globules captured therein (due to emulsification or/and emulsification and physical entrapment phenomena). The process parameters involved in the preparation of the said products derived from experimental and inventive work and ensured the attainment of the desirable characteristics of the "thin-film" in resulting product. Failure to stably incorporate the added oil, results not only in the oil being exudated onto the external surface of the product, but also to structural deformation of the resulting product, with pockets of liquid oil inside its mass. The pictures below compare the two.

Stable incorporation of (5%) olive oil in entire-muscle based meat products, following the method of the patent under examination.



Non-efficient incorporation of olive oil in entire-muscle based meat products



Applicant therefore respectfully submits that neither Domazakis nor Hendriks nor Brandt nor any legitimate combination thereof teaches or suggest all of the limitations of claim 3.

### III. Conclusion

Applicant respectfully submits the claims and the application are in condition for allowance and

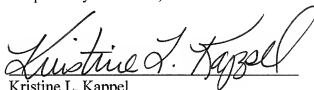


such is courteously solicited. If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct such fees from Deposit Account No. 11-0160.

Respectfully submitted,

Date: \_\_\_\_\_

2/9/11



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